

REMARKS

Claims 1, 3, 5 through 7 and new Claim 8 are pending in the application.

Claim 1 has been amended to emphasize the advantageous neutralization and reuse of carrier material within the inventive methods. Support for this amendment can be found in the Application-as-filed, for example on Page 4, lines 10 – 20.

Claim 8 has been added to complete the record for examination and highlight advantageous embodiments of the invention. Claim 8 is directed to advantageous methods in which the thermal treatment is an infra red heat treatment. Support for Claim 8 can be found in the Application-as-filed, for example on Page 5, lines 8 through 10.

Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

*The Claimed Invention is Patentable
in Light of the Art of Record*

Claims 1, 3 and 5 through 7 stand rejected over United States Patent No. 4,562,020 (“US 020”) to Hijiya et al. in view of United States Patent No. 4,079,106 (“US 106”) to Goldsworthy et al.; United States Publication No. 2003/0228196 to Satchwell and United States Patent No. 5,112,220 (“US 220”) to Wimberger et al.¹

It may be useful to briefly consider the invention before addressing the merits of the rejection.

¹ Applicants respectfully submit that United States Publication No. 2003/0228196 (“US 196”) has matured into United States Patent No. 6,840,712 (“US 712”). Accordingly, remarks directed to US 712 are intended to distinguish US 196, as well.

Drugs, confectionary and the like (hereinafter referred to as "consumables") are known for consumption in sheet-like, wafer-like or film-like forms (hereinafter referred to as "film-form"). Various production processes are known for the manufacture of film-form consumables.

In general, film-form consumables are manufactured on fully automated production lines by forming thin sheets of an active-ingredient film on a carrier material. The active-ingredient containing film is then typically peeled off of the carrier material and the separated active-ingredient containing film cut into suitably sized and shaped pieces for administration. The separated carrier material is taken up onto a reel.

Unfortunately, during the film-form production process the active-ingredient (as well as any additional adjuvants or other coating compounds) can penetrate into the carrier material due to diffusion. The carrier material is then contaminated by these substances, up to their respective degree of saturation. Consequently, once the active ingredient containing film has been peeled off the carrier material, the contaminated carrier material can not be used again, since it is loaded to a non-specified degree with diffused active ingredients and the like (hereinafter referred to as "contaminants," as noted above). If the carrier were to be coated a second time, the active ingredients, etc. would penetrate to a different extent, due to the contaminants already present within the carrier. Thus the composition of the resulting active ingredient containing film could change significantly. This is especially unacceptable for the film-form administration of drugs, making any further use of the carrier material almost impossible.

The present invention provides a method for the removal of substances which penetrate into the carrier material during the production process, resulting in the recited treated carrier material that is essentially contaminant-free free and which can be used again, for example in the production of further film-form consumables.

Altogether unexpectedly, Applicants have found that such contaminants can be evaporated from carrier materials using simple thermal treatments performed at moderate temperatures and dwell times, such as at a temperature of approximately 80 °C for approximately 0.5 to 6 minutes, and the evaporated contaminants can then be permanently disposed of by feeding the evaporated contaminants to a thermal after-burner using controlled air circulation, as recited in the claimed invention.

The decontaminated carrier material, also referred to as neutralized carrier material, may then be reused as a carrier within active-ingredient film forming process, as recited in Claim 1 as-amended.

In particularly advantageous embodiments, the thermal treatment is an infra-red heat treatment, as recited in newly added Claim 8.

The cited references do not teach or suggest the claimed invention.

US 020 is merely directed to the use of a filled glucan to form self-supporting films having sufficient strength. (Col. 2, lines 22 – 31). An aqueous glucan solution is cast onto a corona-treated belt, dried and released. (Col. 2, lines 16 – 23). US 020 generically notes that the glucan film “may be, if necessary” admixed with any of generic ingredients. (Col. 3, lines 25 – 35). US 020 dries its films using warm or hot air, which it notes on several occasions. (Col. 3, lines 42 – 45; Col. 4, lines 27 – 30; Col. 5, lines 30 – 35; *inter alia*).

Evidencing conventional wisdom, US 020 does not teach or suggest the subsequent cleaning of its belt. Applicants respectfully submit that the “regeneration” of US 020 refers to corona-treatment which is well known in the art to promote wet-out of aqueous solutions and further known to decay over time.

As correctly noted by the Examiner in the outstanding Office Action on Page 3, third paragraph, US 020 does not teach or suggest decontamination. This is not surprising in light of the fact that US 020 merely notes in passing that its films “may be, if necessary” admixed with further ingredients. In fact, Applicants respectfully submit that the inventive thermal treatment would not be expected to be required in the absence of the recited active-ingredient.

US 020, merely generically noting a list of optional ingredients, thus does not teach or suggest the recited active-ingredient- containing coating cast onto carrier material such that substances within the coating penetrate into and contaminate the carrier material, much less subjecting such contaminated carrier material to a thermal treatment.

US 020 can not teach or suggest feeding the removed contaminants or other undesired substances to a thermal after-burning using controlled air circulation.

And US 020 most certainly does not teach or suggest such thermal treatments performed at a temperature of approximately 80 °C for approximately 0.5 to 6 minutes.

US 020, repeatedly noting hot air drying of its glucan film, likewise can not teach or suggest such thermal treatments in the form of an infra red heat treatment, as recited in newly added Claim 8.

Applicants thus respectfully submit that the claimed invention is patentable in light of US 020, considered either alone or in combination with the remaining art of record.

The secondary references do not cure the deficiencies in US 020.

US 106 is directed to the continuous fabrication of three-dimensional filament reinforced polyurethane foam insulation. (Col. 1, lines 55 – 60). Liquid/molten polymer is applied to three dimensional filaments disposed on the surface of a belt which has been coated with a wax or an equivalent release agent. (Col. 2, lines 25 - 28 and 44 – 45). After curing sufficiently, the

foamed material is “cut” from the belt. (Col. 2, lines 39 – 41). After cutting the cured/dried material from the belt, the belt is cleaned and subsequently re-coated with a wax or release agent. Suitable cleaning methods include mechanical cleaning and solvent cleaning. (Col. 2, lines 43 – 47).

US 106, directed to reinforced foam formed on a wax coated belt, does not teach or suggest the recited active-ingredient- containing coating, much less such coating cast onto carrier material such that substances within the coating penetrate into and contaminate the carrier material. In contrast to the Office Action’s urgings on Page 4, first partial paragraph, Applicants respectfully submit that the reinforced foam of US 106 would not be expected to penetrate into the belt, due to US 106’s required wax or release coating. Applicants respectfully submit that the penetration of debris left after cutting the foam from the belt in US 106 is purely conjecture.

US 106 thus can not teach or suggest that substances penetrating into a carrier material can essentially all be removed by a thermal treatment, as further recited in the claimed invention. Applicants respectfully submit that there would have been no motivation in the production of reinforced polyurethane foams to remove “essentially all of the contaminants,” as such foams are not in any way intended for human consumption. Hence the removal of “essentially all of the contaminants” would have added unnecessary expense.

Nor does US 106, generically noting “cleaning,” teach or suggest feeding the removed contaminants or other undesired substances to a thermal after-burning using controlled air circulation. The Office Action’s urgings on Page 4 that the thermal cleaning of US 106 would result in gaseous waste is, at best, conjecture. Applicants respectfully submit that any cleaning of foam debris could well be expected to form liquid, rather than gaseous waste.

And US 106, generically noting any of a number of cleaning procedures, most certainly does not teach or suggest such thermal treatments performed at a temperature of approximately 80 °C for approximately 0.5 to 6 minutes.

US 106 likewise fails to teach or suggest such thermal treatments in the form of an infrared heat treatment, as recited in newly added Claim 8.

Applicants thus respectfully submit that the claimed invention is patentable in light of US 106, considered either alone or in combination with the remaining art of record.

US 712 is directed to methods of cleaning contaminated flowable solid media, such as contaminated soil and the like, via one or more thermal screw conveyors. (Col. 3, lines 19 – 32). Hot, inert gas is injected through a plurality of openings in a screw conveyor contained within a vacuum housing. (Col. 3, lines 43 – 65). The temperatures within the screw conveyors range from 235 °C up to 649 °C. (Col. 11, lines 35 -46). In the highest temperature “pyrolysis” zone, an organic binder may be added to encapsulate contaminants. (Col. 3, lines 39 – 40 and Col. 7, lines 23 – 27). In the alternative, the volatiles are removed from the vacuum housing are introduced into a forced air cooler or refrigeration system where the volatiles are “cooled and condensed.” (Col. 9, lines 63 – 65).

US 712, directed to a heated screw conveyor to treat contaminated soil, does not teach or suggest the recited active-ingredient- containing coating which dries into a film, much less such coating cast onto carrier material such that substances within the coating penetrate into and contaminate the carrier material.

US 712 thus can not teach or suggest that substances penetrating into a carrier material can be removed by a thermal treatment such that the carrier material may be re-used, as recited Claim 1 as-amended.

Nor does US 712, teaching either encapsulation or condensation of volatile contaminants, teach or suggest feeding the removed contaminants or other undesired substances to a thermal after-burning using controlled air circulation.

And US 712, teaching pyrolysis temperatures of up to 649 °C, most certainly does not teach or suggest such thermal treatments performed at a temperature of approximately 80 °C for approximately 0.5 to 6 minutes.

US 712 likewise fails to teach or suggest such thermal treatments in the form of an infrared heat treatment, as recited in newly added Claim 8. US 712 instead requires hot gas emitted via a screw conveyor.

Applicants thus respectfully submit that the claimed invention is patentable in light of US 712, considered either alone or in combination with the remaining art of record.

Applicants respectfully reiterate that US 220 is directed to air floatation driers for graphic arts that use solvent-laden air as a combustion medium in generating high drying temperatures. (Col. 1, lines 14 – 19 and Col. 2, lines 45 - 51). US 220's driers are intended to dry ink on paper using a raw gas burner. (Col. 6, lines 1 – 6 and 20 - 23). US 220 expressly notes dryer temperatures of up to 500 °F (i.e. 260 °C) as suitable. (Col. 6, lines 6 – 7). As correctly noted by the Examiner, US 220 is altogether silent as to treatment duration.

US 220, directed to the drying of combustible solvents on a paper web, does not teach or suggest carrier materials or methods for removing contaminants from carrier materials, much less carrier materials which have been contaminated during formation of an active-ingredient-containing-film, as recited in the claims. US 220 is instead merely directed to the drying of combustible solvents from self-supporting paper webs intended for direct consumption.

Thus US 220 can not teach or suggest reusing carrier material, as recited in Claim 1 as-amended.

Nor does US 220, teaching drying temperatures of up to 260 °C, teach or suggest advantageous methods in which essentially all contaminants are removed from a carrier material using a thermal treatment performed at a temperature of approximately 80 °C, as recited in

Claim 1 as-amended. US 220 instead teaches away from such moderate temperatures by expressly noting its use of high drying temperatures. Applicants further respectfully submit that the recited 80 °C (176 °F) does not “correspond” to 93 °C (200 °F) as urged within the outstanding Office Action on Page 4, last partial paragraph. Nor would there have been any motivation for US 220, directed to graphics arts drying, to have significantly lowered its bottommost temperature range. Applicants respectfully submit that one skilled in the graphic arts would instead have been motivated to operate at the top of US 220’s temperature range in order to increase drying speed and thereby produce more of the printed graphics.

And US 220, altogether silent as to dryer dwell time, most certainly does not teach or suggest advantageous methods in which the thermal treatment is performed for a period of time of up to 6 minutes, as further recited in Claim 1.

US 220, solely directed to air drying, likewise fails to teach or suggest such thermal treatments in the form of an infra red heat treatment, as recited in newly added Claim 8. US 712 instead teaches use of an exhaust stream heated by a gas burner.

Applicants respectfully reiterate that the claimed invention is not taught or suggested by US 220, considered either alone or in combination with the remaining art of record.

Applicants respectfully submit that there would have been absolutely no motivation to have combined the foregoing references. US 020 is directed to the use of a filled glucan to form self-supporting films. US 106 is directed to three-dimensional filament reinforced foam insulation. US 196 is directed to screw conveyors to decontaminate soil. US 220 is directed to graphic arts dryers using ink solvent as a combustion medium. These are altogether different fields of endeavor and problems solved, to say the least.

However, even if the foregoing references were combined (which Applicants did not do), the claimed invention would not have resulted.

The combination particularly does not teach or suggest the recited active-ingredient-containing films formed from coating cast onto carrier material such that substances within the coating penetrate into and contaminate the carrier material, much less subjecting such contaminated carrier material to a thermal treatment sufficient to allow its re-use. As correctly noted by the Examiner, US 020 does not teach or suggest decontamination. US 106 is directed to reinforced foam blocks formed on a wax-coated belts, and merely generically notes that its belts may be cleaned using a number of methods. US 220, directed to graphic arts dryers, does not have a carrier material. US 712, directed to soil decontamination, likewise does not include a carrier material.

Nor does the combination teach or suggest feeding the removed contaminants or other undesired substances removed from such a carrier material to a thermal after-burning using controlled air circulation. US 712 instead teaches the cooling and condensation of volatiles removed from its contaminated soils.

And the combination most certainly does not teach or suggest such thermal treatments performed at a temperature of approximately 80 °C for approximately 0.5 to 6 minutes. US 020 does not teach or suggest decontamination. US 220 expressly notes temperatures of up to 260 °C to dry solvent from ink. US 712 teaches temperatures of up to 649 °C to clean contaminated soil. US 106 is silent as to any cleaning temperatures.

And the combination, altogether silent as to heat treatments other than hot air/gas, can not teach or suggest such thermal treatments in the form of an infra red heat treatment, as recited in newly added Claim 8.

Applicants thus respectfully submit that the claimed invention is patentable in light of US 020; US 106; US 712 and US 220, considered either alone or in any combination.

CONCLUSION

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1, 3 and 5 through 8 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

Cathy Moore

Cathy R. Moore
Reg. No. 45,764

ProPat, L.L.C.
425-C South Sharon Amity Road
Charlotte, NC 28211-2841
Telephone: (704) 365-4881
Fax: (704) 365-4851
Customer No. 38263

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Claire Wygand
Claire Wygand